REMARKS

Petition for Extension of Time Under 37 CFR 1.136(a)

It is hereby requested that the term to respond to the Examiner's Action of January 4, 2006 be extended two months, from April 4, 2006 to June 5, 2006 (June 4 being a Sunday).

Authorization to charge a Credit Card is given to cover the extension fee. The Commissioner is hereby authorized to charge any additional fees associated with this communication to Deposit Account No. 19-5425.

In the Office Action, the Examiner indicated that claims 1 through 68 are pending in the application and the Examiner rejected all claims. Claim 21 has been amended to insert the word "claim" to clarify the dependency on claim 1. Claim 46 has been amended to depend on claim 1. Claim 48 has been amended to depend on claim 4. Claim 62 has been amended to correct a typographical error.

All of the pending claims have been rejected in a series of ten §103 rejections. Each of the Examiner's §103 rejections is discussed below in the order in which the rejections were presented.

Claim Rejections, 35 U.S.C. §103

In item 3 on page 2 of the Office Action, the Examiner rejected claims 1, 4, 6-9, 11-14, 16, 21-24, 28-30, 33-36, 38, 42-44, and 66-67 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,991,729 to Barry et al. in view of U.S. Patent No. 6,368,797 to Schappert. The Examiner's rejection is discussed below following summaries of the Barry et al. and Schappert patents.

U.S. Patent No. 5,991,729 to Barry et al.

U.S. Patent No. 5,991,729 to Barry et al. teach methods to generate medical counseling information. A diagnostic code is entered following examination of a patient and a report is compiled from textual and graphic information specific for that diagnostic code. The methods of the invention provide a diagnostic and patient education tool which can also provide useful information to the physician.

There is no disclosure of identifying a research subject.

U.S. Patent No. 6,368,797 to Schappert

U.S. Patent No. 6,368,797 to Schappert ("Schappert") teaches a method to identify patients at risk for neurological diseases, especially Alzheimer's, based on testing for allelic variants of GPIIIa or GPIIb and forecasting the outcome/suitability for entering patients into clinical drug trials. The invention in Schappert is based on the realization that patients with Alzheimer's were almost four times more likely to have mutations in both the GPIIIa and GPIIb allele.

Claim 1 and claim 24, the independent claims included in this rejection, are directed to methods for *identifying research subjects* based on obtaining medical data from a subject and *matching this data* with *criteria* for a research project. As discussed below, Barry et al. does not teach identification of a research subject and Schappert is based on testing to determine

susceptibility to a given disease state(s) based on genetic markets. Neither patent renders obvious using data from subjects to match those subjects with suitable research projects.

To support this §103 rejection, the Examiner has stated "As per claim 1, Barry et al. teaches a method for identifying a research subject". This is a mischaracterization of Barry et al. Barry et al. is directed to providing information to a patient and/or the patient's physician. The methods of Barry et al. are not used to identify potential research subjects, but instead are used to provide a medical report to a patient to aid the patient in treating and understanding his disease state. (In claim 24, the research subject is a donor, such as a blood donor.)

The cited art also fails to meet the claimed requirement of matching the patient's medical data with certain criteria for a research project. In presenting this rejection, the Examiner has specifically cited the Barry et al. Abstract; column 4, lines 8-15; column 4, lines 26-31; column 4, lines 33-48; and column 5, lines 53-62. (There is no mention of identifying a research subject in the Abstract.) Barry et al. disclose obtaining medical information from a subject in column 4, lines 8-15, in this example, diagnosing "Barrett's Esophagus". As explained in column 4, lines 26-31, the diagnostic code for Barrett's esophagus is entered into a relational database. As stated in column 4, lines 33-35 "A patient specific medical counseling report is generated by the relational database . . ." This passage illustrates the purpose of the invention in Barry et al. - to provide information to a patient on his condition. In presenting this rejection, the Examiner appears to rely primarily on the characterization of column 5, lines 53-62 as "extracting an identification from the first database, wherein said

identifier is associated with a subject matching the identified criteria." This section of Barry et al. actually states:

> "Preferred embodiments of memory storage devices comprise a memory storage device, such as magnetic tape, magnetic hard drive disk, or an optical CD-ROM disk, having stored thereon a digitized report compiled from retrieved and inserted archived textual and graphical information that is specific for a unique diagnostic code selected as a result of an analysis of a biological sample from at least one patient. The stored report identifies the patient, discloses the results of the sample analysis, and addresses the report to the physician for that patient."

This does not relate to "extracting an identification from a first database ...". All that is being done here is to link a patient to that patient's own medical data and data on that patient's disease. The Examiner further indicates that this section goes on to match the identifier from the first database with the name and contact information in order to identify the research subject. Again, there is no mention of identification of research subjects in Barry et al. Barry et al. are not trying to locate research subjects, but instead, help patients understand their disease.

The Examiner has acknowledged that Barry et al. do not teach the step of identifying criteria for a research subject. To overcome this gap in Barry et al., the Examiner has relied on U.S. Patent No. 6,368,797 to Schappert (hereinafter "Schappert"). In particular, the Examiner has cited the portion of Schappert (column 12, lines 43-52) which reads:

> "Further, either alone or in combination with other health data, the variant GPIIIa and GPIIb alleles can be used to predict a subject's outcome by comparing the subjects GPIIIa and GPIIb genotypes (and other health data) to a patient database containing the GPIIIa and GPIIb genotypes (and other health data) of

> similarly afflicted subjects. Based on this database comparison, a subject's likely outcome, i.e., progression of disease, cure rate, response to therapy, morbidity and mortality, can be statistically assessed."

As seen in this quote, the focus is not on the identification of research subjects from a pool of prospective research subjects, but instead on using genomic information from one subject and comparing this patient's genotype to a patient database of similarly afflicted subjects. Simply put, Schappert teaches looking at the genotype of other patients for prognosis/treatment of Alzheimer's disease. The purpose in reviewing the database information is to assess the best treatment and most likely outcome for a patient.

The presently claimed methods are directed to the identification of research subjects. One of skill in the art would not turn to the disclosures of Barry et al. and Schappert to obtain the claimed invention. Furthermore, there is no motivation to combine Barry et al. with Schappert. Basically stated, Barry et al. does not provide a research subject, but provides a patient who, by the methods in Barry et al., is provided with additional information about his disease state. Schappert does not provide a motivation to look for a research subject. In fact, as described in column 2, lines 15-26, a subject may already be in a clinical trial. Schappert is directed to identifying subjects at risk for Alzheimer's disease based on GPIIIa and GPIIb alleles and providing an existing patient with a prognosis for his disease. Furthermore, when both Barry et al. and Schappert are combined, they still fail to provide an essential feature of the claimed invention: the identification of research subjects based on review of certain

criteria. In view of the above, applicants respectfully request the Examiner to reconsider and withdraw the rejection.

In item 4 on page 6 of the Office Action, the Examiner rejected claims 2 and 25 under 35 U.S.C. §103(a) as being unpatentable over Barry et al. in view of Schappert as applied to Claims 1 and 24 above, respectively. Claims 2 and 25 depend on claims 1 and 24, respectively, and recite that informed consent is obtained from the subject. Given the patentability of claims 1 and 24 based on the arguments above, applicants request this rejection be withdrawn.

At item 5 on page 7 of the Office Action, the Examiner rejected claim 3 under 35 U.S.C. [§103(a)] as being unpatentable over Barry et al. in view of Schappert, and further in view of U.S. Patent No. 5,626,144 to Tacklind. A discussion of this rejection follows below after a discussion of Tacklind et al.

U.S. Patent No. 5,626,144 to Tacklind et al.

U.S. Patent No. 5,626,144 to Tacklind et al. ("Tacklind") teaches a system to monitor a patient with a disease state such as, for example, asthma. The system sends data to a remote computer system which records longitudinal data, and time stamps this data. Tacklind describes an asthma monitoring system and the use of a relational database to store

information on a patient, using longitudinal data in the form of measured values with time stamps. The data can then be put into a report format and provided to a physician.

The Examiner has cited column 5, lines 55-63 and column 6, lines 5-13, of Tacklind stating that one would be motivated to obtain means of pairing a patient with a remote sensor and a subscription pairing a device ID with a care provider.

Applicants submit this rejection is based on a misunderstanding of the subject matter of claim 3. While claim 3 is directed to obtaining data longitudinally, this is fundamentally different from Tacklind, which is directed to a remote sensor that provides continuous monitoring of a subject. There is no analogous remote reporting system in the present invention.

In the present invention, data would be added "longitudinally" as a person was examined or provided biological samples over time by a physician or technician. In contrast, the system in Tacklind does not require a physician or technician to input data or take a sample. Rather, a remote sensing device is used to measure parameters, such as those listed in column 5, lines 26-38 and a sensor output communicates this information via the telephone system. Applicants further submit that Tacklind has been misapplied as a reference because the methods of the present invention would be considered to teach away from the methods in Tacklind. In particular, Tacklind is based on the need for real-time/constant monitoring of a patient, whereas the present invention has no such requirement. Based on these fundamental differences and the arguments presented above with respect to Barry et al. and Schappert, applicants request the Examiner withdraw this rejection.

At item 6 on page 7 of the Office Action, the Examiner rejected claim 46 under 35 U.S.C. §103(a) as being unpatentable over Barry et al. in view of Tacklind. Applicants have amended claim 46 to depend on claim 1. At item 7 on page 8 of the Office Action, the Examiner rejected claim 48 under 35 U.S.C. §103(a) as being unpatentable over Barry et al. in view of Tacklind.

Claims 46 and 48 are similar and, as such, will be discussed together. These claims define biological samples associated with an identifier that are collected and stored longitudinally. To support this rejection, the Examiner has cited Tacklind (column 5, lines 55-63 and column 6, lines 5-13). The longitudinal data recordation in Tacklind, as discussed above, is a remote reporting system that does regular updates automatically and reports these updates by the telephone system. This is fundamentally different from the sample collection and storage of claims 46 and 48, which relates to long-term manual collection of samples over time. Claim 48 is additionally distinguished over Barry et al. and Tacklind in that the samples are taken at a collection establishment. Tacklind is intended to provide continuous monitoring of a chronic disease condition which is distinguished from sample collections over time to see, for example, if a patient's genome can provide useful indicators for the development of disease.

At item 8 on page 8 of the Office Action, the Examiner rejected claim 49 under 35 U.S.C. §103(a) as being unpatentable over Barry et al. in view of Tacklind. (Based on the

discussion presented by the Examiner on pages 9 and 10 of the Office Action, Applicants believe the Examiner may have meant to also include claims 50-53 and 59-61 in this rejection. The arguments presented below for claim 49 would also apply to claims 50 to 53 and 59 to 61.)

Claim 49, and the claims which depend on claim 49, define a method for creating a database. As discussed above, Tacklind is directed to instantaneous, ongoing monitoring. Tacklind clearly does not disclose a number of the steps in claim 49, including steps (c), (d) and (e). In particular, there is no mention of deriving proteomic and genomic information from a sample, storing the sample in a location from which it can be recovered, and associating the data with an identification that can be used to locate the samples. In view of these missing and non-obvious steps, the Examiner is requested to reconsider and withdraw the rejection of claim 49.

At item 9 on page 10 of the Office Action, the Examiner rejected claims 5, 27 and 68 under 35 U.S.C. §103(a) as being unpatentable over Barry et al. in view of Schappert and further in view of U.S. Patent No. 5,915,240 to Karpf. This rejection is discussed below following a discussion of Karpf.

U.S. Patent No. 5,915,240 to Karpf

U.S. Patent No. 5,915,240 to Karpf ("Karpf") teaches a reference computer system for access to medical information over a computer network. The network includes a number of

elements: a medical look-up "client" program, a medical look-up "server" program, and a medical "call server". The server provides a central database for a single type of medical information. The client program maintains a local database for a variety of types of medical information. The client program automatically updates itself from the servers. A network chat facility (med call) allows the user to engage in real-time communication with a person at a help site who can provide assistance to the user.

Claims 5, 27, and 68 all relate to situations in which the donor is a deferred donor. The concept of deferred donor is discussed in column 14, lines 27-34. Applicants acknowledge that the term "deferred donor" was known in the art. However, the Examiner's rejection is not supported by the Barry et al. and Schappert patents as discussed above. The Examiner has additionally cited column 14, lines 31-33 of Karpf which mentions a "blood donor disease deferral database". As acknowledged by the Examiner, Barry et al. do not teach the step of identifying criteria for a research subject. Schappert simply provides methods for telling a patient the possible outcome of his disease and determining a preferred therapy. All that Karpf adds is the notion of a "deferred donor". Given the failure of Barry et al. to identify a subject, the fact that Karpf discloses the existence of deferred donors does not overcome the basic flaw in this §103 rejection. Simply finding the term "deferred donor" in a piece of prior art and substituting this term for "subject" in the broader claims on which claims 5, 27 and 68 depend, does not overcome the deficiencies in this §103 rejection. None of the art cited by the Examiner alone or in combination provides a method for identifying a research subject. This is because the art relied upon by the Examiner is directed to

fundamentally different types of medical databases, all of which focus on specific but unrelated tasks. In view of the basic flaws in the Barry et al. and Schappert patents, and the fact that Karpf does not provide the missing gaps in these patents, but only provides the term "deferred donor", the Examiner is requested to reconsider and withdraw this rejection.

At item 10 on page 10 of the Office Action, the Examiner rejected claims 9-10, 14-15, 31-32, and 36-37 [under 35 U.S.C. §103(a)] as being unpatentable over Barry et al. in view of Schappert, and further in view of U.S. Patent No. 6,730,477 to Sun. A discussion of this rejection follows below, after a discussion of Sun et al.

U.S. Patent No. 6,730,477 to Sun et al.

U.S. Patent No. 6,730,477 to Sun et al. ("Sun") is directed to methods for diagnosing, monitoring and staging breast cancer based on analyzing changes in levels of breast specific genes (BSG) in cells.

The Examiner has cited Sun (column 6, line 61 to column 7, line 8; column 7, lines 10-23; and column 8, lines 31-49) stating that medical data comprises pharmacogenomic, genomic or proteomic data as evidenced by Sun. The passage relied on by the Examiner discusses known assay techniques for identifying mutations that may be useful in the methods of Sun for diagnosing, monitoring, and staging breast cancer. Applicants do not dispute that medical data may include genomic and proteomic data. However, Sun does nothing to overcome the deficiencies of Barry et al. and Schappert since it provides no information on

using the information to identify a research subject. Accordingly, Applicants request the Examiner to withdraw this rejection.

At item 11 on page 11 of the Office Action, the Examiner rejected claims 55-58 and 62-65 [under 35 U.S.C. §103(a)] as being unpatentable over Barry et al. in view of Tacklind and further in view of Sun.

Claims 55 to 58 define the nature of the genomic or proteomic information provided by the method of claim 49. Claims 62 to 65 are directed to methods for identifying a genomic or proteomic characteristic which correlates with a disease. Claim 62 has been amended to depend on claim 49. Accordingly, all of the rejected claims depend on claim 49. As discussed above in the Examiner's rejection of claim 49, neither Barry et al. nor Tacklind disclose steps (c), (d), (e), and (f), Sun et al. discloses proteomic/genomic monitoring of BSGs. Claim 49 is directed to a method for creating a database. In contrast, the cited patents are directed to (1) informing a patient about his disease (Barry et al.); (2) real-time monitoring of a patient's disease (Tacklind); and (3) monitoring breast cancer in a patient (Sun). Accordingly, all three patents are directed to helping patients with a diagnosed disease state, not to creating a longitudinal database. as recited in claim 49.

At item 12 on page 11 of the Office Action, the Examiner rejected claims 17-20 and 39-42 under 35 U.S.C. §103(a) as being unpatentable over Barry et al. in view of Schappert, as applied to claims 1 and 24 above, respectively.

The Examiner is respectfully directed to the discussion of the rejection of claims 1 and 24 above. Claims 17 to 20 and 39 to 42 relate to methods which utilize a second database. Given the deficiencies of the Barry et al. and Schappert patents, and the requirements of claims 17-20 and 39-42 which recite the additional requirement of a second database, applicants request this rejection be withdrawn.

Conclusion

The present invention is not taught or suggested by the prior art. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection of the claims. An early Notice of Allowance is earnestly solicited.

The Commissioner is hereby authorized to charge any additional fees associated with this communication to Deposit Account No. 19-5425.

Respectfully submitted

June 5, 2006
Date

Patrick J. Kelly, Ph.D., Esquire
Registration No. 34,638

SYNNESTVEDT & LECHNER LLP
2600 ARAMARK Tower
1101 Market Street
Philadelphia, PA 19107

Telephone: (215) 923-4466
Facsimile: (215) 923-2189